REMARKS/ARGUMENTS

Reconsideration of the application is requested.

Claims 1-15 are now in the application. Claims 1 and 5 have been amended. Claims 11-15 have been added.

Support for the "guide" that was added to claims 1 and 5 is found in the original specification. Reference is had, for example, to Figs. 7 and 8, where the needle guide 17 is shown at the top of the assembly, and to the description on page 12.

Support for the new claim 11 is found in Figs. 2 and 3 and the corresponding description. Further support is found in the description of Fig. 8 on page 11, bottom paragraph, of the specification.

Support for claims 12-15 is found in the specification as well. Reference is had, in particular, to Fig. 9, which illustrates the protective cap assembly with the integrated needle as a separate functional unit from the syringe.

We now turn to the art rejection, in which claims 1, 4, 5, 9, 10 were rejected as being anticipated by Lee et al. (US 5,201,721, "Lee") under 35 U.S.C. § 102. We respectfully traverse.

Lee has a protective sheath 28 formed essentially of an open cylinder. The forward end is open. That is, Lee's protective cap 28 does not "completely" encase the sharps element.

Claims 1 and 5, as originally filed, had the protective cap completely encasing the sharps element (claim 1) and the hypodermic needle (claim 5). It appears the Examiner may have overlooked the limitation. Claims 1 and 5, as originally filed, were clearly not anticipated by Lee.

To briefly recap the applicable law: Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of a claimed invention as well as disclosing structure which is capable of performing the recited functional limitations. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984). W.L. Gore and Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1554, 220 USPQ 303 (Fed. Cir. 1983). In other words, a claim is anticipated if a single reference, either expressly or inherently, discloses every limitation of the claim at issue. In re Schreiber, 128 F.3d 1473 (Fed. Cir. 1997). Here, Lee does not disclose the limitation that the sharps element or the needle is completely encased in the protective cap.

Even if, arguendo, we were to stretch the meaning and interpret the "completely encasing" language very broadly, the open top of Lee would still not satisfy the required element. Applicant carefully explained the limitation in the specification. Reference is had, for example, to page 12 of the specification. There, the exit

opening at the top of the cap is limited to the "largest rated needle diameter" and the remaining opening (to be pierced on first use of the device) is sealed with a membrane.

In light of the foregoing, we should discuss the rejection of claims 1 and 5 in the context of 35 U.S.C. § 103. The Examiner presented a prior art reference which indeed teaches a protective membrane, namely, Olovson (US 2002/0193749 A1). Olovson has a protective cylinder 2 similar to the cylinder 28 of Lee. The secondary reference further teaches that a membrane 2b may be provided at the end-part 2a. The membrane 2b is to seal off the inner diameter of the tube. See, p. 4, [0073]. Olovson further explains that his protective cap "consists essentially of a section of tubing with a circular cross-section and constant radius . . . " and that the membrane is very thin ("membrane thickness much less than the thickness of the tube 2' material," p. 4, [0074]).

If one were to use the pertinent teaching of Olovson and provide a thin membrane to the sheath 28 of Lee, one could probably consider the resulting protective cap to form a "completely encasing cap," at least until the membrane is pierced.

Claims 1 and 5, as amended, call for a needle guide (or a sharps guide) at the forward end of the protective cap. The needle guide ensures that the opening at the tip is as small as possible and that the exposure towards the luer lock is minimized. This aids in maintaining proper sterility of the assembly. Further, the guide aids in

bracing the needle during use at the very forward end and thus adding a further element of stability to the assembly.

Neither structure nor functionality is met by the thin membrane of the reference teachings. The very thin membrane of Olovson is provided to maintain sterility of the system prior to its use. While the reference does not provide any details, it is safe to assume that once the membrane is pierced it is probably destroyed (e.g., ripped). More importantly, the thin membrane cannot function as a guide for the needle and it certainly does not brace the needle.

The combined teachings of Lee and Olovson, therefore, to not render obvious the invention of claims 1 and/or 5 under 35 U.S.C. § 103.

Similarly, the combination of Lee with Grabis et al. (US 6,322,540 B1) does not render the claimed invention obvious either. Grabis et al. are concerned with the head attachment, i.e., the mounting of the protective cap to the barrel. The secondary reference also has a completely open cylinder forming the protective cap.

In fact, the disclosure of Grabis et al. is quite useful in showing how the invention differs from the prior art. There, a completely separate assembly with a ring 3 and a cylinder 10 is attached to the barrel of the syringe. The needle and the luer lock are not impacted and they remain completely separate from the protective cap.

Applicant – as illustrated in Fig. 9, for example – provides for a different solution. Here, the protective cap and the needle form a unit and that unit is attached to the syringe via the luer lock. This is specifically recited in claim 12.

Claim 12 is patentable over the references. None of the prior art references show or suggest a protective cap assembly that does not compromise the syringe itself. Here, we have a protective cap and needle assembly, which is connected *in toto* to the luer lock of the syringe. It is a self-contained assembly that can be retrofitted to an existing syringe without structurally changing the syringe or attaching anything to the syringe barrel or the head.

In other words, applicant's device is a separately attached luer-locked device. The syringe or the syringe barrel is not compromised. In an advantageous modification, the novel assembly defines two or more functional needle positions, for instance, for shallow injections and for deep injections.

In summary, none of the references, whether taken alone or in any combination, either show or suggest the features of claims 1, 5, and/or 12. These claims are, therefore, patentable over the art and since all of the dependent claims are ultimately dependent thereon, they are patentable as well.

In view of the foregoing, reconsideration and allowance of claims 1-15 are solicited.

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